IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' RENEWED *DAUBERT* MOTION TO EXCLUDE THE OPINIONS OF JAMES E. RAFALSKI

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INTRODUCTION

Plaintiffs' proffered expert, James Rafalski, offered the facially implausible testimony that ***more than 90%*** of the orders for vital pain medicines that Defendants received from their pharmacy customers in Cabell/Huntington should have been "flagged" and blocked (*i.e.*, not shipped) because they were likely to be diverted. That unreliable testimony, like Mr. Rafalski's other core opinions, was unsupported by any methodology or data and should be excluded under Rule 702.

Mr. Rafalski's opinion that each of the millions of orders flagged by his analyses were "more likely than not" diverted is pure *ipse dixit*, unsupported by anything more than his unexplained say-so. That opinion—and Mr. Rafalski's other *ipse dixit* opinions—were divorced from any reliable methodology or data.

Moreover, the methodology underlying Mr. Rafalski's 90% figure is untethered from any reliable foundation: (i) he invented his flagging methodologies for litigation; (ii) no one, including him, the DEA, or any wholesale distributor, has used them outside of litigation; (iii) he applied them without even reviewing the orders he claimed were likely to be diverted; (iv) he could not say whether any orders shipped by Defendants should have been reported as "suspicious" under regulations implementing the Controlled Substances Act; and (v) his methodologies are admittedly disconnected from any evaluation of medical need or changing medical practice.

Mr. Rafalski testified that each of the millions of orders flagged by his analysis should not have been shipped. Yet he also acknowledged that if wholesale distributors "arbitrarily imposed limits on prescription opioids, that could … deprive medication from people who needed it." 5/26 Tr. at 184:12–20. It is difficult to imagine anything more arbitrary—and anything more likely to

deprive patients of needed medicines—than refusing to fill more than 90% of the orders placed by State-licensed and DEA-registered pharmacies in an entire county and city.

Given these and other infirmities, it is unsurprising that Mr. Rafalski's flagging methodologies flunk each component of the test identified by the Supreme Court in *Daubert*. Indeed, Mr. Rafalski ***admitted*** that his methodologies (i) have never been tested; (ii) have not been subject to peer review or publication; (iii) have a 400% error rate; and (iv) have no general acceptance in his field. The Court should therefore exclude Mr. Rafalski's opinions in their entirety.

BACKGROUND

DEA regulations state that wholesale distributors and other registrants "shall provide effective controls and procedures to guard against theft and diversion of controlled substances," including by designing and operating systems "to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. §§ 1301.71, 1301.74. The regulations define "suspicious orders" as including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.* § 1301.74.

Plaintiffs offered former DEA diversion investigator James Rafalski as a putative expert "in the field of diversion control investigations, Suspicious Order Monitoring Systems, and maintenance of effective control[s] to prevent diversion of controlled substances into the illicit market." 5/26 Tr. at 30:8–14. Defendants moved to exclude Mr. Rafalski's testimony both before trial and when he was proffered by Plaintiffs as an expert at trial.[1] The Court indicated that it would "hear the testimony and reserve ruling." 5/26 Tr. at 32:20–21, 33:9–15. At the conclusion

[1] *See* Defs.' *Daubert* Mot. to Exclude the Opinions of James E. Rafalski (Dkt. No. 1052); 5/26 Tr. at 30:16–32:19.

of Mr. Rafalski's testimony, Defendants renewed their motion, and the Court requested further briefing. 5/27 Tr. at 52:16–57:8.

Mr. Rafalski's testimony was based on six different flagging methodologies that he—relying on the data analyses of Dr. Craig McCann—purports to use to identify "suspicious" orders of oxycodone and hydrocodone that Defendants supposedly should have, but failed to, identify, block, and/or report. 5/26 Tr. at 84:12–95:21. On direct examination, Mr. Rafalski presented each of these six methodologies as bases for his opinions, without distinguishing between them in terms of their reliability or utility. *Id*. On cross-examination, however, he immediately disavowed four of those six methodologies (Methodologies C–F). 5/26 Tr. at 224:25–225:12. He testified that, "if someone was to come to me and say should I use these methodologies, … ***I would tell them no***." *Id.*[2] He further testified that, "[i]f I owned a company, a distributor, and I was going to design a suspicious order system, ***I would not use*** [***Methodologies C–F***]." *Id*.

Mr. Rafalski testified that Method A was the "right" model. 5/26 Tr. at 219:5–24. Method A flags any order whose total volume exceeds (even by one pill) the largest order placed by a pharmacy in the preceding 6 months—effectively imposing for all time a monthly cap that can never exceed the largest order placed in the first six months of ordering, no matter how long ago that was or whether circumstances have changed over time. 5/26 Tr. at 231:15–19. In addition, Method A "***assum***[***es***] that distributors did not conduct any diligence on the first flagged suspicious order," and therefore flags ***all*** subsequent orders—no matter how small or innocuous—placed by the same pharmacy for all time. 5/26 Tr. at 227:1–9.

[2] All emphasis added unless noted.

Using this methodology, Mr. Rafalski arrived at the facially unreliable conclusion that around ***90% of all orders placed by Defendants' pharmacy customers were likely to be diverted.*** 5/26 Tr. at 96:13–97:18. Specifically, he opined that

- for AmerisourceBergen, 90.6% of oxycodone and 91.1% of hydrocodone shipments were likely to be diverted, 5/26 Tr. at 96:20–25;
- for Cardinal Health, 93.1% of oxycodone and 82.5% of hydrocodone shipments were likely to be diverted, 5/26 Tr. at 97:1–3; and
- for McKesson, 87.9% of oxycodone and 87.4% of hydrocodone shipments were likely to be diverted, 5/26 Tr. at 97:4–6.

Mr. Rafalski's and Plaintiffs' inability to even articulate the purpose of his flagging methodologies in consistent or coherent terms demonstrates the self-evidently unreliable nature of his opinions. For example, Mr. Rafalski repeatedly referred to his flagged orders as "suspicious" and therefore as orders that should be blocked, *see, e.g.*, 5/26 Tr. at 97:7–17, only to disavow on cross-examination any claim that all of the flagged orders were necessarily "suspicious orders" within the meaning of the governing regulations:

> Q…. Do you know how many of these tens of millions of [flagged] orders should have been reported to the DEA as suspicious?
>
> A. No, I do not.

5/26 Tr. at 229:24–230:2. Similarly, Mr. Rafalski emphatically asserted that "every one of those tens of millions of orders were likely to diverted," 5/26 Tr. at 214:10-12 ("More likely than not, yes, sir."), only to back away from that claim and contend only that the "pills ***could*** have the ***potential*** for diversion," 5/26 Tr. at 217:2–20. Finally, after boldly asserting that "90 percent of the pills should not have been shipped," *id.* at 217:2-5, Mr. Rafalski abandoned that claim when asked how many cancer patients would be denied treatment by his methodology: "It's not saying that none of these 90 percent would actually have been distributed." *Id.* at 217:15-17.

According to Mr. Rafalski, Method A—and Method B, which he created after Method A was criticized in depositions—were based on the program discussed by the D.C. Circuit in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017). Yet, on cross-examination, Mr. Rafalski admitted that his methodologies are only "stylized illustrations," 5/26 Tr. at 222:1–4, do not "precisely implement any Suspicious Order Monitoring System used in the real world," 5/26 Tr. at 220:14–19, and do not mirror the systems actually discussed in *Masters*, *see, e.g.*, 5/26 Tr. at 235:10-16 & Ex. 1[3] (admitting that Method A "was not used in the Masters program in the real world"), 5/26 Tr. at 238:13–21 (claiming that Method B was "similar" to *Masters* but admitting that there were "difference[s]").

Mr. Rafalski further admitted that he:

- created both methodologies for purposes of litigation, 5/26 Tr. at 222:11–13;
- never used his methodologies while he was at DEA, 5/26 Tr. at 222:5–10;
- never recommended that DEA or others use them, 5/26 Tr. at 222:21–223:11;
- never attempted to have them published or peer-reviewed, 5/26 Tr. at 223:12–17;
- never used them for any purposes other than as a paid expert witness in litigation, 5/26 Tr. at 223:18–21;
- is unaware of anyone in the real world ever adopting them, 5/26 Tr. at 220:14–19;
- ignored the admitted fact that an increase in opioid prescribing by doctors caused a substantial increase in the volume of orders placed by pharmacies in Cabell/Huntington since the beginning of the time-period covered by his analysis, 5/26 Tr. at 242:6–19; and
- ignored the admitted fact that, from 2003 to 2013, DEA was steadily increasing its production quota for prescription opioids, based on its determination that there was a growing medical need for the medicines, 5/26 Tr. at 180:7–181:1, 181:14–182:1.

[3] Exhibit 1 is the transcript of the video deposition testimony that was played in open Court at 5/26 Tr. 235:12.

Unsurprisingly, Mr. Rafalski was forced to admit that neither methodology is "generally accepted." 5/26 Tr. at 236:12–15, 242:1–5.

Method A. Mr. Rafalski's preferred methodology—Method A—incorporates an ***assumption*** that Defendants did no due diligence to clear the "suspicion" surrounding the initial order. Based on that assumption, he opines that once an initial order is flagged, all subsequent orders should also have been flagged. Mr. Rafalski conceded, however, that there is no sound factual or methodological basis for this assumption because:

- the no-due-diligence assumption is contrary to the methodology outlined in *Masters*, 5/26 Tr. at 235:1–21;
- he was "not aware of any company or regulator who has ever" applied the "[no-]due-diligence assumption to any set of data at any point in time," 5/26 Tr. at 236:7–11; and
- it "wouldn't be a valid exercise for the DEA to attempt to use [the assumption] to identify diversion," 5/26 Tr. at 236:19–23.

While Mr. Rafalski tried to justify his no-due-diligence assumption after-the-fact by claiming that he did not see sufficient evidence of diligence in the "customer files" he reviewed in the discovery record, 5/26 Tr. at 102:14–17, his own testimony showed that there is no basis for that assumption. He admitted that he does not know, "of those initial flagged orders under Method A, how many between 0 and 100 percent were actually investigated and the flag cleared by the defendants." 5/26 Tr. at 228:21–229:6. He also conceded that no regulation says that diligence files—many of which would be decades old—must be retained. 5/26 Tr. at 269:21–25. And Mr. Rafalski further admitted that he does not know whether documents were not produced in this litigation because they never existed or merely because the documents used to exist and "weren't kept" by Defendants up through the time that litigation commenced. 5/27 Tr. at 12:23–13:6.

The uncontradicted record evidence demonstrates that each Defendant ***did*** do substantial diligence:

- ABDC's Vice President of Diversion Control and Security, David May, testified that after onboarding a customer, ABDC "will continue to monitor each and every order of controlled substances and listed chemicals by that customer." 5/17 Tr. at 26:23–27:9; *see also id.* at 37:25–39:6 (Mr. May describing the due diligence ABDC conducts when reviewing customer orders, including "past ordering activity of that particular controlled substance by that customer over a period of time," reviewing certain data and spreadsheets, and reviewing "the customer due diligence file itself"). Further, ABDC's Vice President of Regulatory Affairs, Steve Mays, testified that ABDC would "typically do additional due diligence on the customer" when a threshold increase was requested. 5/18 Tr. at 82:6–13.

- Cardinal Health's former Vice President of Anti-Diversion, Michael Mone, testified that "every order that triggers is going to have some sort of due diligence." 5/21 Tr. at 62:18–63:3; *see also* 5/21 Tr. at 65:2–14 ("There's going to be a basis for the pharmacist member of the team to make a decision [regarding changing a threshold]."); *see also* CAH-WV-00743 (SOP detailing due diligence procedures for orders that trigger customer thresholds).

- McKesson's Director of Regulatory Affairs, Michael Oriente, testified that "[t]here was constant due diligence done" before raising thresholds, and that he would review a specific customer and their history before granting an increase. 5/24 Tr. at 181:10–25; *see also* 5/25 Tr. at 65:18–23 ("Q. [D]o you conduct diligence in the context of making decisions about whether to increase, or decrease, or keep thresholds the same? A. Yes. Before each threshold review is done, there would be due diligence conducted by myself.").

Method B. Mr. Rafalski developed Method B only after he was deposed by Defendants and subjected to criticism regarding, among other things, his due diligence assumption. 5/26 Tr. at 226:8–13. Method B is (according to Mr. Rafalski) "generally" the "same" as Method A, 5/26 Tr. 224:14–18, except that it eliminates the no-due-diligence assumption. 5/26 Tr. at 226:14–25. This single change creates a "big difference" in the numbers: Method A's numbers are 400% larger than Method B's numbers. 5/26 Tr. at 219:10–22. The reason for this large difference is that many of the orders that Mr. Rafalski assumed to be "suspicious" under Method A merely because a prior order was flagged are not independently "suspicious" under his so-called *Masters* approach.

LEGAL STANDARD

Under Rule 702, expert testimony must be "based on sufficient facts or data" and "the product of reliable principles and methods." Fed. R. Evid. 702(b), (c). The district court must

"ensure that any and all scientific testimony … is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993)). As this Court has recognized, "[t]he touchstone of whether a witness may testify as an expert under Fed. R. Evid. 702 is … whether he would be 'helpful,' but it is helpfulness to the *trier of fact*, not to a party's case, that counts." Memorandum Opinion and Order (Dkt. No. 1262) at 3 (quoting *Hardin v. Ski Venture, Inc.*, 50 F.3d 1291, 1296 (4th Cir. 1995)) (emphasis in original).

In assessing the reliability and admissibility of putative expert testimony, courts look to four factors: "(1) whether [the] theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether [the] technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Cooper*, 259 F.3d at 199 (citing *Daubert*, 509 U.S. at 592–94). For the reasons explained below, Mr. Rafalski's testimony fails all four factors.

ARGUMENT

As Mr. Rafalski's testimony revealed, his opinions are not supported by a methodology—let alone a reliable one. Unrestrained by any methodology, he offered the patently implausible testimony that ***more than 90%*** of the orders for prescription opioids shipped Defendants to their pharmacy customers in Cabell/Huntington were "more likely than not" diverted, and so Defendants' delivery of those medicines was a "substantial factor" in causing diversion in Cabell/Huntington.

Nor did he provide any support for the "flagging" methodology that generated his implausible 90% figure. Neither the DEA nor any wholesale distributor has ever actually used

Mr. Rafalski's invented-for-litigation methodology, which he arrived at without even looking at the flagged orders and which ignored the conceded growth in legitimate opioid prescribing during the time period covered by his analysis. In short, Mr. Rafalski's flagging methodologies are unreliable, fail each of the four *Daubert* factors, and so should be excluded.

I. THE COURT SHOULD EXCLUDE MR. RAFALSKI'S *IPSE DIXIT* OPINIONS.

At the conclusion of Mr. Rafalski's direct testimony, Plaintiffs' counsel elicited a series of *ipse dixit* opinions from Mr. Rafalski. These opinions were that:

- all of the purportedly "suspicious" orders identified by Mr. Rafalski's flagging methodologies were "likely to be diverted into the illicit market in Huntington-Cabell County";
- Defendants failed to "maintain effective control to prevent diversion of prescription opioids" or "design[] and operate[] an effective system to identify, block and report suspicious orders arising out of Huntington-Cabell County"; and
- "these systemic failures were a substantial factor in the diversion of prescription opioids into the illicit market in Huntington-Cabell County."

5/26 Tr. at 107:21–112:2, 112:22–113:3. But, while on the stand, Mr. Rafalski never even attempted to establish a reliable methodology underlying those opinions. Nor did he articulate any basis in the record for those opinions. Moreover, on cross-examination, Mr. Rafalski admitted a series of facts that directly undermine and contradict his opinions. Because all of Mr. Rafalski's opinions are factually and methodologically unsupported, they should be excluded. *See, e.g.*, *Cooper*, 259 F.3d at 203 ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").[4]

[4] *See also Belville v. Ford Motor Co.*, 919 F.3d 224, 234 (4th Cir. 2019) (affirming exclusion of expert who's methodology "seemed artificially induced to produce a desired result and did not reflect real-world results" and therefore "was partly *ipse dixit*"); *McEwen v. Baltimore Washington Medical Center Inc.*, 404 Fed. Appx. 789, 2010 WL 5129873, at *1–2 (4th Cir. Dec. 14, 2010)

A. Mr. Rafalski's Opinion That All Orders Identified By His Flagging Methodologies Are "More Likely Than Not" To Be Diverted Should Be Excluded.

Mr. Rafalski's *ipse dixit* opinion that "every one" of the "tens of millions of orders" identified by his flagging methodologies were "[m]ore likely than not" "to be diverted" should be excluded under Rule 702. 5/26 Tr. at 214:6–12. As a threshold matter, Mr. Rafalski entirely failed to establish any methodological basis for his stunning opinion that more than 90% of the orders Defendants shipped were more likely than not diverted. While he described how he flagged orders, he did not describe the procedures or criteria he used to reach his diversion conclusion—because there were none. He did not describe the academic literature or DEA guidance that he relied on in forming his opinion—because there is none. He did not set forth any methodology for distinguishing between (i) an order that might be flagged as unusually large but is self-evidently benign (such as a double-sized weekly order placed by a pharmacist who is going on vacation the following week[5]), and (ii) an order that truly bears an indicia of potential diversion[6]—because he had none, and instead assumed that ***all*** flagged orders were likely to be diverted.

(affirming trial court's exclusion of expert testimony where expert's causation opinion was "'a[n] *ipse dixit* statement of a clinician saying that I think causation has been proved, which is simply not sufficient as a matter of law'"); *Holesapple v. Barrett*, 5 Fed. Appx. 177, 2001 WL 208490, at *2 (4th Cir. Mar. 2, 2001) (affirming exclusion of "perfect example of an *ipse dixit* opinion" where expert based his opinions about boating injury only on his general experience without considering any factors about the particular incident).

[5] 5/24 Tr. at 47:16–23 (testimony of Michael Oriente); *see also* 5/26 Tr. at 204:12–205:7 (Mr. Rafalski agreeing that volume could change and legitimate orders could meet the statutory definition of "suspicious" if, for example, a Cancer Center opened nearby or a local pharmacy shut down).

[6] At all relevant times, Defendants' systems blocked and did not ship orders that were identified as likely to be diverted. *See, e.g.*, 5/12 Tr. at 203:11-17 (ABDC's Senior Vice President of Corporate Security and Regulatory Affairs, Chris Zimmerman, testified that if ABDC knew a pharmacy was diverting drugs "we wouldn't be selling [opioids] to them"); 5/20 Tr. at 230:10-14 (Cardinal Health's Vice President of Anti-Diversion, Michael Mone, testified that the company never shipped an order it believed would be used for other than legitimate medical purposes); 5/25

Mr. Rafalski, moreover, admitted a number of facts that directly contradict his *ipse dixit* opinion that all of his "flagged" orders were likely to be diverted and also that demonstrate his lack of competence to offer any such opinion. For example, Mr. Rafalski admitted that he

- did not know "how many" of the "suspicious orders that have occurred over time" were "actually diverted," 5/26 Tr. at 205:18–22;
- did not "actually review any of the orders" that he concluded "were likely to be diverted" before rendering his opinions, 5/26 Tr. at 214:13–15, 215:1–7;
- did not assess the medical need for prescription opioid medications in Cabell County and does not "know how many of those orders went to fill legitimate medical need," 5/26. Tr. at 129:4–7, 216:13–18, 216:23–217:1, 218:15–20;
- did not identify "a single doctor … in Cabell County or Huntington who was prescribing improperly or engaging in diversion," 5/26 Tr. at 128:11–15;
- was not "aware of any pills that were shipped by [Defendants] that ended up filling a prescription that was dispensed other than in response to a licensed prescriber writing a prescription," 5/26 Tr. at 131:6–10.
- did not know what percentage of the orders he identified as likely to be diverted "were actually investigated and … cleared" by Defendants, 5/26 Tr. at 228:21–6;
- did not know how many of those orders were suspicious on their face or "should have been reported to the DEA as suspicious," 5/26 Tr. at 227:25–228:3, 229:24–230:2;
- did not consider that, when DEA was tasked by Congress to estimate "how much diversion is occurring," it estimated "less than .1 percent diversion" for oxycodone and hydrocodone, and did not undertake "the type of calculation of actual diversion that the DEA has conducted," 5/26 Tr. at 249:11–250:13; and
- did not consider that the West Virginia Board of Pharmacy had expressly determined that a Rite-Aid pharmacy in Cabell/Huntington—to which McKesson shipped over one million dosage units of hydrocodone and oxycodone during the relevant time period that, according to Mr. Rafalski, were likely to be diverted[7]—was, in fact, a "GOOD PHARMACY!" for

Tr. at 48:4–14, 55:12–20, 126:4–8 (McKesson's Director of Regulatory Affairs, Michael Oriente, confirming that at all relevant times McKesson blocked orders that it identified as likely to be diverted). Mr. Rafalski, after watching the testimony of these witnesses, did not dispute this fact.

[7] *See* Trial Ex. P-43225 at 13, 17 (detailing McKesson's distribution of hydrocodone and oxycodone to Rite Aid #968 in Cabell County from 2006 to 2014).

which "all prescriptions appear prescribed for a legitimate medical use," 5/27 Tr. at 25:14–26:20 & Trial Ex. DEF-WV-01989.

In several other ways, Mr. Rafalski's own trial testimony further demonstrated the unreliability of his facially implausible assertion that upwards of 90% of all orders filled by Defendants were likely to be diverted:

First, Mr. Rafalski acknowledged that, during the period covered by his analyses, "legitimate" prescribing of opioids increased significantly. 5/26 Tr. at 242:6–11, 244:7–13. Yet his methodology, by design, ignores all real-world changes that affect distribution levels, *see id.* at 241:8-12, including shifts in medical need, increases in the DEA quota, population shifts, and other demographic changes, *id.* 241:17-25, 245:9-12; *see also id.* at 242:1-5 (admitting that he could not identify any generally accepted methodology "that ignores entirely what the medical community is doing in terms of increased legitimate prescriptions"). When the dominant driver of increased opioid shipments was an increase in legitimate prescribing—as Mr. Rafalski admitted[8]—it is fundamentally unsound to use a methodology that fails to consider that critical fact. 5/26 Tr. at 245:4-8 (admitting that his methodology would flag a large number of prescriptions "just by normal growth in prescriptions").

Second, Mr. Rafalski admitted that small and entirely innocent changes in ordering patterns could dramatically alter the results of his flagging analysis—and thus the number of orders that are, in his opinion, likely to be diverted. Under Mr. Rafalski's Method A, an increase of just 100 pills in ordering for a calendar month can result in *all* future orders by that pharmacy being flagged—even if offset by a 100-pill decrease in the following month. 5/26 Tr. at 231:3–232:2;

[8] 5/26 Tr. at 242:15–20 ("You get the prescription, that goes up, and then the distribution goes up, correct? A. That's correct. *No other way for those charts to increase without prescriptions*. Q. No other way, right? A. That's correct.").

see infra p.23–25. There is simply no reliable basis for assuming that a one-month shift in the timing of an order for 100 pills converts ***all*** subsequent orders by a pharmacy from legitimate orders to orders that are likely to be diverted. Yet, that is precisely the opinion Mr. Rafalski offered.

The closest Mr. Rafalski ever came to offering an explanation for his opinion was his assertion that, unless some due diligence is done on a flagged order, no additional orders should be shipped to that customer, and his corresponding assumption that no diligence was in fact performed. *See* 5/26 Tr. at 77:8–14, 79:10–25. But Mr. Rafalski offered no basis for his assertion, and his assumption is contradicted by the evidentiary record. *See supra* p.7. Moreover, even accepting as true Mr. Rafalski's opinion that flagged orders should not be shipped, there is a massive analytical gap between that opinion and the further opinion that all flagged orders were likely to be diverted—a gap Mr. Rafalski never attempted to bridge. *See also* 5/26 Tr. at 204:12–16 (acknowledging that "there are all kinds of circumstances when an order can be of unusual size, pattern or frequency, but not be diverted"). Accordingly, the Court should exclude Mr. Rafalski's *ipse dixit* opinion that each of the millions of orders flagged by his methodologies were more likely than not diverted.

B. Mr. Rafalski's Opinion That Defendants Failed To Design Adequate Systems To Maintain Effective Controls Against Diversion And To Identify And Block Suspicious Orders Should Be Excluded.

Mr. Rafalski's *ipse dixit* opinion that Defendants failed to maintain effective controls against diversion and to design a system to identify and block suspicious orders is likewise unfounded.[9] Here, too, Mr. Rafalski did not describe any reliable *methodology* in forming his

[9] Mr. Rafalski's opinion that Defendants failed to "maint[ain] effective controls against diversion," *see* 21 U.S.C. § 823, also should be excluded because it states a legal conclusion. *See, e.g.*, *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013) ("In the Fourth Circuit, opinion

opinion: he merely stated that he reviewed Defendants' policies and procedures, as well as whatever "customer files" remained in existence and were produced in discovery. While Mr. Rafalski purported to describe Defendants' suspicious order monitoring systems in general terms, *see generally* 5/26 Tr. at 60–77, at no point did he actually explain ***how or why*** Defendants' suspicious order monitoring policies were deficient.

Mr. Rafalski's own testimony, moreover, fatally undermined the reliability of this opinion. Most notably, Mr. Rafalski's principal criticism of Defendants was that their systems failed to block "suspicious orders." Specifically, according to Mr. Rafalski, the *Masters* decision requires wholesale distributors either to (i) block a suspicious order or (ii) conduct additional diligence and only ship the order if that diligence clears the suspicion. 5/26 Tr. at 88:20–89:2. Tellingly, however, Mr. Rafalski admitted that (1) at all times since 2008, each Defendant designed and operated a suspicious order monitoring system that ***did not ship specific flagged orders***, 5/26 Tr. at 207:2–6, and (2) orders that are not shipped cannot be diverted, 5/26 Tr. at 208:3–9.

To be sure, systems that used different criteria—like the flagging criteria that Mr. Rafalski (but no actual wholesale distributor) relied on—would likely have flagged a different subset of orders. But Mr. Rafalski did not opine at trial that the specific thresholds actually used by Defendants to identify and block orders during this time-period were set improperly. Instead, he merely criticized Defendants for failing to conduct due diligence on orders that were not flagged by Defendants' systems but would have been flagged if Defendants had instead been using one of his (deeply flawed) methodologies.[10]

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testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.") (quoting *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)).

[10] Defendants' systems did not systematically block all "suspicious orders" prior to 2008. But, as Mr. Rafalski acknowledged, the DEA understood and accepted that distributors would report and

Mr. Rafalski attempted to justify his opinions by asserting that he did not see sufficient evidence of customer-level diligence in the files that were produced by Defendants and made available to him. 5/26 Tr. at 102:4–17. But his assumption that the absence of more complete customer files in Defendants' litigation productions means that no diligence was done is deeply flawed and contrary to the evidence.[11] *First*, Plaintiffs themselves called representatives of each Defendant in their case, and the unequivocal testimony of those company witnesses establishes that each Defendant did substantial due diligence before increasing thresholds, *i.e.*, the maximum amount of opioid medications that they would deliver to their pharmacy customers. *See supra* p.7. *Second*, Mr. Rafalski admitted that there is nothing in the regulations governing Defendants that required them to retain "diligence files" from the early mid-2000s or earlier. 5/26 Tr. at 269:21–25. And he further admitted that he did not know whether documents were not produced simply because "they weren't kept" long-term by Defendants, not because they never existed to begin with. 5/27 Tr. at 12:23–13:6. Accordingly, there is no basis for Mr. Rafalski's inference that the absence of certain customer files for periods pre-dating the commencement of this litigation establishes (or even tends to suggest) that Defendants did not conduct adequate due diligence before increasing customer thresholds.

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then ship such orders at that time. 5/26 Tr. at 259:6–24. Indeed, Mr. Rafalski testified that (1) the governing regulations do not include an express "do not ship" requirement, 5/26 Tr. at 255:6–9, and (2) the DEA in 2007 advised industry of its "new interpretation" of those regulations purporting to set for a "do not ship" requirement, 5/26 Tr. at 256:24–258:21. *See also id.* at 251:9–13 (Rafalski admitting that he is not aware "of a prior public occasion when the DEA said any order you identify as suspicious should not be shipped prior to … 2007").

[11] *See, e.g.*, *Trana Discovery, Inc. v. S. Rsch. Inst.*, 915 F.3d 249, 255 (4th Cir. 2019) (concluding that "[a]n expert must offer an opinion that fits the case at hand" and methodologies "that simply ignore[] key evidence veer[] into speculation"); *United States v. Walton*, 86 F.3d 1154 (4th Cir. 1996) (holding that "opinion of the expert must fit the facts" and affirming exclusion of expert testimony that was contrary to record evidence).

In short, Mr. Rafalski's opinions regarding the purported deficiencies in Defendants' suspicious order monitoring programs is not based on any reliable methodology and is unsupported by any facts or data. It also is contrary to all record evidence. Accordingly, the Court should exclude that *ipse dixit* opinion.

C. Mr. Rafalski's Opinion That Defendants' Alleged Failures Were A "Substantial Factor" In The Diversion Of Prescription Opioids In Cabell/Huntington Should Be Excluded.

The Court also should also exclude Mr. Rafalski's *ipse dixit* opinion that the alleged deficiencies in Defendants' suspicious order monitoring systems "were a substantial factor in the diversion of prescription opioids into the illicit market in Huntington-Cabell County."[12] As an initial matter, the opinion is entirely dependent on the predicate opinion that Defendants' systems were inadequate. Because that opinion should be excluded, this opinion too is not admissible.

In addition to that threshold defect, Mr. Rafalski's "substantial factor" opinion is not based on any reliable methodology provided in the course of Mr. Rafalski's testimony. Indeed, Mr. Rafalski was not even asked to explain how he arrived at this "substantial factor" opinion. Mr. Rafalski never discussed, much less explained, the methodology he used to reach his opinion—nor did he provide any demonstration that the methodology (if there was one) is generally accepted and reliable.

Mr. Rafalski's own testimony demonstrates that he could not possibly sponsor his "substantial factor" opinion under the rules governing expert testimony. Under his theory, Defendants' alleged monitoring failures led to their shipping an excessive number of pills to their

[12] Mr. Rafalski's "substantial factor" opinion, which relates directly to Plaintiffs' (incorrect) understanding of the legal standard for proximate causation in a public nuisance case, should also be excluded because it states a legal conclusion. *See supra* n.9.

pharmacy customers in Cabell/Huntington. But Mr. Rafalski expressly disclaimed any opinion about "whether diversion occurred at a pharmacy level" in Cabell/Huntington and whether any pharmacy chains (such as Rite Aid) "helped cause the opioid crisis in Cabell/Huntington."[13] 5/26 Tr. at 135:8–13, 137:12–21. He also could not identify a single pill that was shipped by Defendants and "that ended up filling a prescription that was dispensed other than in response to a licensed prescriber writing a prescription." 5/26 Tr. at 131:6–10. Absent some connection between (i) the alleged deficiencies in Defendants' suspicious order monitoring programs and (ii) any diversion occurring at Cabell/Huntington pharmacies, Mr. Rafalski has no basis on which to opine that those alleged deficiencies contributed (substantially or otherwise) to diversion in Cabell/Huntington.

Plaintiffs doubtless will argue that some of the pills that Defendants shipped to their pharmacy customers and were then dispensed by those pharmacies to patients based upon legitimate prescribing by doctors were ***subsequently*** diverted into the illegal market. But Mr. Rafalski admitted that Defendants are ***not*** responsible for that form of diversion:

> Q. You agree that when a patient misuses medication that was prescribed for a legitimate medical use, whether it's giving it away or selling it, the ***patient*** is responsible for that?
>
> A. Yes, sir.

[13] Although Mr. Rafalski nominally provided a conclusory opinion about McKesson's purported lack of diligence with respect to Rite Aid, *see* 5/26 Tr. at 106:2–21, he readily conceded facts showing that he had no basis for it. In particular, Mr. Rafalski: (1) admitted that documentation of diligence might be missing due simply to the passage of time, 5/27 Tr. at 17:6–12; and (2) admitted that he lacked basic knowledge about the relevant Rite Aid stores in Cabell/Huntington, including how many there were, whether they remained McKesson customers, what their ordering levels were, and whether they were above or below the norm, 5/27 Tr. at 16:2–17:5. Mr. Rafalski further admitted that he had failed entirely to consider the fact that the West Virginia Board of Pharmacy had expressly determined that one of McKesson's Rite Aid customers in Cabell/Huntington was a "GOOD PHARMACY!" for which "all prescriptions appear prescribed for a legitimate medical use." *See supra* p.11–12. Finally, he disavowed any opinion that pharmacy chains such as Rite Aid "helped cause the opioid crisis in Cabell/Huntington." 5/26 Tr. at 135:8–13, 137:12–21.

> …
>
> Q. You agree that when a prescription is legitimately written and dispensed, distributors have no control over what happens to it after that point?
>
> A. That's a correct statement.

5/26 Tr. at 196:7–11, 198:19–22. Third-party criminal conduct that occurs ***after*** prescription opioid medicines are properly dispensed by Defendants' pharmacy customers cannot justify Mr. Rafalski's assertion that Defendants' conduct was a substantial factor in bringing about diversion. 5/26 Tr. at 195:1–196:11 (agreeing that "diversion from the medical cabinet" involves "crimes or potential crimes" by parties other than distributors).

Mr. Rafalski's "substantial factor" opinion fails for yet another reason: he admittedly did not make any attempt to consider the conduct of any other person or entity besides Defendants.[14] Mr. Rafalski opined that "everybody" played a role in bringing about the opioid crisis and that "thousands of people and companies contributed to the opioid crisis in Cabell County." 5/26 Tr. at 122:23–123:3, 186:18–15. Despite this, he did not even attempt to consider the contributions of those people and entities before concluding that Defendants' contributions to diversion were "substantial" in comparison to those of others. *See Cooper*, 259 F.3d at 202 ("[I]f an expert utterly fails to consider alternative causes or fails to offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert's testimony."); *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Prac. & Prods. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 645 (4th Cir. 2018) (affirming exclusion of expert who "failed to adequately explain

[14] *See, e.g.*, 5/26 Tr. at 116:1–6 ("The plaintiff lawyers in this case only asked you to evaluate the three defendants in this case; correct? A. That's correct, Your Honor. Q. You did not evaluate any companies the plaintiff lawyers are not suing in this case. True? A. I did not, Your Honor, only the three defendants.").

the basis for ruling out other contributing factors—including some that she herself described as substantial," rendering opinion mere *ipse dixit*).

For example, Mr. Rafalski agreed that Defendants are not responsible for diversion that occurs from patients' medicine cabinets. *See* 5/26 Tr. at 195:1–198:22. And Mr. Rafalski took no issue with statistics showing that "[m]ore than three out of four people who misuse prescription pain-killers use drugs *prescribed* to someone else." 5/26 Tr. at 199:11–18. Yet he offered no explanation how Defendants could be a "substantial factor" in diversion when by his admission at least three-quarters of diversion had nothing to do with Defendants. 5/26 Tr. at 186:2–17.

Mr. Rafalski, moreover, acknowledged that ***doctors*** have the responsibility to "determin[e] medical need when they write prescriptions for opioids;" that "DEA does not expect distributors to second-guess the legitimate medical judgments of prescribers;" and that "doctors bear some responsibility for the opioid crisis." 5/26 Tr. at 116:15–19, 117:8–17, 123:17–20. Yet again, Mr. Rafalski failed to explain how Defendants could be a substantial factor given the acknowledged central role of doctors in determining usage levels in Cabell/Huntington. 5/26 Tr. at 186:2–17.

Mr. Rafalski also ignored the contributions of other entities that he admitted played a role in bringing about the opioid crisis:

- **DEA**. Mr. Rafalski admitted that the DEA played a role in bringing about the opioid crisis. 5/26 Tr. at 184:23–10. For example, the DEA is responsible for setting annual production quotas for prescription opioids each year based on its estimation of the legitimate "medical, scientific, research, and industrial needs of the United States." 5/26 Tr. at 180:7–18; *see also* 21 U.S.C. § 826. The DEA consistently raised its opioid production quotas during the relevant time period; for instance, the quota for oxycodone "increased over 400 percent from 34,482 kilograms in 2002 to a high of 153,750 kilograms in 2013." 5/26 Tr. at 181:14–182:1. Mr. Rafalski was "aware that [the DEA had] been criticized for their handling of the quota," yet admitted that he did not make any effort to consider the role of the DEA. 5/26 Tr. at 181:3–7.

- **Manufacturers**. Mr. Rafalski has elsewhere opined that opioid manufacturers "helped cause the opioid crisis." 5/26 Tr. at 11–14. He expressed the opinion that Purdue—which, according to Rafalski, "conducted an extensive campaign to market and promote

Oxycontin"—was "a factor that contributed to the abuse and diversion of Oxycontin." 5/26 Tr. at 141:18–6, 143:13–16. Yet Mr. Rafalski made no effort to consider the contributions of Purdue or any other manufacturers to diversion in Cabell/Huntington. 5/26 Tr. at 144:24–145:17, 186:2–17.

- **Other Distributors**. Mr. Rafalski made no effort to consider the contribution of other wholesale distributors besides Defendants who shipped opioid medicines into Cabell/Huntington. 5/26 Tr. at 150:13–1. Mr. Rafalski did not dispute Dr. McCann's testimony that 36 different distributors supply pharmacies in Cabell/Huntington. For example, he made no effort to analyze Miami-Luken's contribution to diversion in Cabell/Huntington, even though he acknowledged that there are "some criminal charges pending against the company." 5/26 Tr. at 161:2–16. Nor did he consider the "amount of" diversion attributable to Miami-Luken's customers, such as the A-Plus Care Pharmacy in Barboursville, 5/26 Tr. at 152:19–22—which was "a major source of supply for pharmaceutical diversion to the tri-state area and beyond" and was shut down by law enforcement in 2014.[15]

In sum, Mr. Rafalski's *ipse dixit* opinion that Defendants were a "substantial factor in the diversion of prescription opioids" in Cabell/Huntington should be excluded because it (i) is based on his unreliable and unsupported opinion regarding Defendants' suspicious order monitoring programs, (ii) is itself not based on a reliable methodology (or any methodology whatsoever), (iii) is belied by his own testimony disavowing any ability to connect Defendants' shipments to diversion, and (iv) fails entirely to consider the contributions of the "thousands" of other entities that he admits played a role in causing diversion in Cabell/Huntington.

II. MR. RAFALSKI'S FLAGGING METHODS ARE UNRELIABLE AND SHOULD BE EXCLUDED.

Mr. Rafalaski testified that Method A—which implausibly flags around 90% of all orders shipped by Defendants into Cabell/Huntington as orders that should have been blocked—is the correct analysis. Because no reliable methodology underlies Method A (or any of his other

[15] *See* Trial Ex. P-41220 (Huntington Police Department 2014 Annual Report) at 20. As Mr. Rafalski acknowledged, Miami-Luken was the *only* supplier of the A-Plus Care Pharmacy. 5/26 Tr. at 152:19–22.

methodologies), and because those methodologies fail each of the four tests articulated by the Supreme Court in *Daubert*, Mr. Rafalski's flagging analyses should be excluded.

On direct examination, Mr. Rafalski presented six different methodologies for "flagging" orders that purportedly give rise to a "suspicion of diversion" and therefore trigger some indeterminate due diligence requirement. *See, e.g.*, 5/26 Tr. at 84:12–95:21. The Court was led to believe that each of the six methodologies served a purpose in identifying suspicious orders. Mr. Rafalski provided only a high-level explanation of how each methodology operated and then read into the record Dr. McCann's analysis of how many orders would have been flagged by each; he did not distinguish between them in terms of their reliability or utility. *Id.*; *see also* 5/26 Tr. at 96:1–101:21. On cross-examination, however, Mr. Rafalski unequivocally disavowed four of his six methodologies. 5/26 Tr. at 224:25–225:12. That he sponsored six flagging methodologies, only to admit on cross-examination that four were unreliable, is reason enough to exclude his testimony in full. *Cf. In re Mirena Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 259 (S.D.N.Y. 2018) (concluding that putative expert's "embrace of these author-repudiated findings is presumptively unsound methodology"), *aff'd sub nom. In re Mirena Prods. Liab. Litig. (No. II)*, 982 F.3d 113 (2d Cir. 2020).

Regarding his two remaining methodologies, Mr. Rafalski further testified that the one that produced the "larger" number of flagged orders—*i.e.*, Method A—was the "right" one. 5/26 Tr. at 219:13–24. Method A purports to identify orders that Defendants should have blocked and not shipped. *See* 5/26 Tr. at 97:7–17. But Method A—which flags tens of millions of orders and would have blocked between ***82-93% of all relevant oxycodone and hydrocodone shipments*** by Defendants into Cabell/Huntington, *see* 5/26 Tr. at 96:13–97:18—produces implausible and manifestly unreliable results. As a result, Method A should be excluded under Rule 702. *See, e.g.*,

Bryte ex rel. Bryte v. Am. Household, Inc., 429 F.3d 469, 477 (4th Cir. 2005) (striking expert opinion that purportedly excluded an alternate cause of a fire because it was contrary to common sense and thus violated *Daubert*'s reliability mandate); *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 467 (S.D.N.Y. 2018) ("In assessing the reliability of an expert opinion, a resort to common sense is not inappropriate."). For many of the same reasons, Method B is also unreliable, unsupported, and subject to exclusion.

A. Mr. Rafalski's Flagging Methodologies Lack Any Methodological Or Factual Basis.

Mr. Rafalski's flagging methodologies lack any grounding in fact or methodology, and therefore should be excluded as unreliable under Rule 702. The following are illustrative examples of how Mr. Rafalski's foundationless methods actually contradict the undisputed record in this case:

- **Defendants' Due Diligence**. Method A—which flags all subsequent orders following an initial triggering event—rests on the assumption that Defendants did not conduct adequate due diligence. *See* 5/26 Tr. at 89:3–9, 101:22–102:3, 226:14–25, 227:1–9. But Defendants' company witnesses testified that due diligence *was* performed, and that testimony belies Mr. Rafalski's bare assumption and erodes the theoretical foundation of Method A. *See supra* p.7.[16] Mr. Rafalski also conceded that the absence of more complete files in Defendants' productions could be due to the fact that certain materials were not retained by Defendants and that nothing in the governing regulations required Defendants to retain customer files. *See supra* p.6, 15.[17]

- **DEA's Diversion Estimates**. On cross-examination, Mr. Rafalski acknowledged that the DEA—the agency that Congress instructed to "estimat[e] … how much diversion is occurring"—has determined that "less than .1 percent" of oxycodone and hydrocodone medications are actually diverted. 5/26 Tr. at 249:11–250:9. Although Mr. Rafalski

[16] Mr. Rafalski further testified that he had been following the trial testimony, which means he repeated on direct examination his no-due-diligence assumption, knowing it had been contradicted by the company witnesses, yet offering no basis for disregarding their testimony. This failure to account for and explain contrary evidence is further reason to treat his assumption, and the conclusions following from that assumption, as unreliable.

[17] *See also* supra n.11 (expert testimony should be excluded when based on assumptions that are contrary to the evidence).

indicated that he "didn't agree" with the DEA's calculation, he gave no basis for doing so and conceded that he has not even attempted his own calculation. Moreover, he provided no explanation as to why Method A produces estimates that are ***93,000% higher*** than the DEA's.

- **Legitimate Prescribing**. The DEA has repeatedly stated that the "overwhelming majority" of physicians who prescribe controlled substances "do so for legitimate medical purposes." 5/26 Tr. at 120:21–121:3. In fact, two senior DEA officials have informed Congress that 99% or more of physicians are prescribing legitimately.[18] 5/26 Tr. at 121:10–122:22. Mr. Rafalski admitted that he agrees with DEA's assessment and that Defendants have no ability or responsibility to second-guess the legitimate medical judgments of prescribers. 5/26 Tr. at 117:8–12, 120:21–121:3, 121:10–122:22, 148:22–149:17. Accordingly, there is no basis to believe that more than 90% of those legitimate prescriptions should have been blocked. If anything, the exact opposite is true.

Under the applicable federal regulations, moreover, "suspicious orders" are defined as orders that are "***unusual***"—whether because of their size, frequency or some other reason. See 21 C.F.R. § 1301.74. As a matter of basic common sense, more than 90% of all orders could not possibly be "unusual."

The unreliability of Method A is further demonstrated by a simple example from Mr. Rafalski's cross-examination. As explained, Method A flags any order whose volume would cause a pharmacy's monthly order total to exceed the order total for the highest of the six preceding months. Thus, if any one order causes the monthly volume to exceed the trailing six-month threshold, the order is blocked and ***all subsequent orders*** of that opioid base code are also blocked. 5/26 Tr. at 96:10–15, 97:7–12, 231:9–13. In the example illustrated in Figure 1 below—which

[18] This is consistent with the testimony of other witnesses offered by Plaintiffs, including Dr. Corey Waller, who testified that doctors who were prescribing opioid medications "were acting in good faith," 5/4 Tr. at 104:15–20, and Dr. Rahul Gupta, the former West Virginia State Health Commissioner, who testified that there are "relatively few prescribers who are violating the standards of care" and that "[t]here were more prescribers trying to do the right thing than those who weren't, meaning in West Virginia there were more good doctors than bad doctors at any one point in time," 5/6 Tr. at 93:20–94:3.

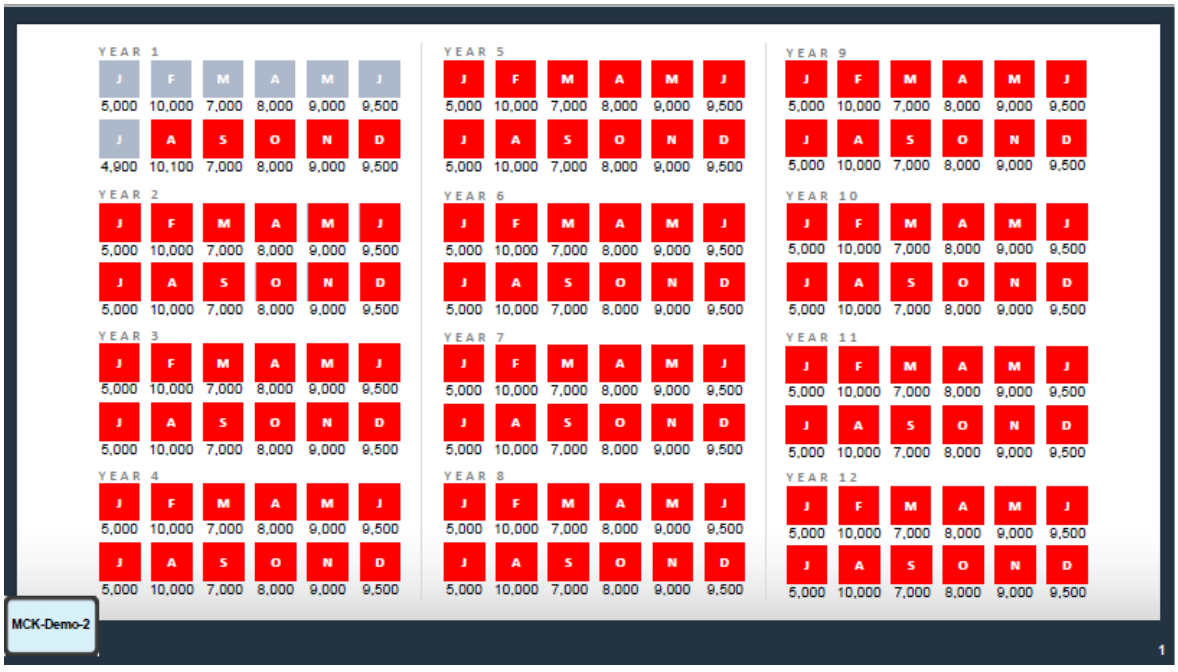
was presented and validated during Mr. Rafalski's cross-examination—a pharmacy has the following ordering pattern in the first six months of Year 1:

January: 5,000
February: 10,000
March: 7,000
April: 8,000
May: 9,000
June: 9,500

If that same pattern repeated itself for the second six months of Year 1—such that 5,000 pills were ordered in July, 10,000 pills were ordered in August, and so on—no orders would ever be flagged.

If, however, that ordering pattern changed ever-so-slightly, the analysis would be markedly different. If the same pharmacy instead ordered 4,900 pills in July and 10,100 pills in August of Year 1, under Method A, ***every single order*** following that one-time variation (totaling more than one million pills in twelve years) supposedly should be blocked and not shipped. That is true even though the 100-pill August excess was offset by a smaller order in the immediately preceding month.

Figure 1: MCK-Demo-2



Mr. Rafalski agreed that this is exactly how Method A is intended to operate. 5/26 Tr. at 230:21–234:25. In fact, Mr. Rafalski conceded that even if every order after the triggering event was only 100 pills—*i.e.*, thousands of pills ***below*** the relevant trailing six-month threshold—each would ***still*** be blocked under Method A. 5/26 Tr. at 234:20–25.

Yet further evidence of the unreliability of Method A is Mr. Rafalski's failure even to consider the orders placed by hospital pharmacies. 5/26 Tr. at 271:1-272:18 ("Q. You're missing other hospitals, correct? A. Yes, hospitals. Only … data that's on display for you, Your Honor, as retail pharmacies as customers."). Mr. Rafalski, however, did not identify any evidence that would provide a basis for saying (i) that diversion from hospital pharmacies was less likely than diversion from other pharmacies or (ii) that hospital doctors were less likely to over-prescribe opioids than any other doctors in Cabell/Huntington. Indeed, the evidence in the record is that all West Virginia doctors received the same "green light" from the West Virginia Board of Medicine to prescribe opioids for chronic pain.[19] His explanation for excluding hospital pharmacy orders from his analysis—"I didn't find it to be applicable to the diversion topic. The diversion is occurring at the retail pharmacy level and to include a hospital wouldn't have been a … a prudent way to look at the distribution," 5/26 Tr. at 271:24–272:6—is *ipse dixit* and no explanation at all.

As discussed, Mr. Rafalski did absolutely nothing to substantiate the extraordinary and facially implausible results produced by Method A. In particular, he admitted that he (1) did not

[19] *See, e.g.*, Trial Ex. MC-WV-01219 (1997 Position Statement by the West Virginia Board of Medicine stating that "opioids are appropriate treatment for chronic non-malignant pain in selected patients"); Trial Ex. MC-WV-01218 (2005 West Virginia Board of Medicine Guidelines stating that "controlled substances including opioid analgesics may be essential in the treatment of acute pain … and chronic pain, whether due to cancer or non-cancer origins); Trial Ex. MC-WV-01935 (2013 West Virginia Board of Medicine Guidelines stating that "opioid analgesics are useful and can be essential in the treatment of acute pain … as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes").

review any of the flagged orders, (2) does not know how many of the flagged orders were actually diverted, (3) does not know what percentage of any "flags" were actually investigated and cleared by Defendants, (4) does not know how many of the flagged orders went to fill legitimate medical need, (5) cannot identify a single doctor in Cabell/Huntington who was prescribing unlawfully or engaging in diversion, (6) cannot identify a single pill shipped by Defendants that was subsequently dispensed unlawfully, and (7) does not know whether diversion occurred from any pharmacy in Cabell/Huntington. *See supra* p.11–12.

In light of these facts and Mr. Rafalski's wholesale failure to actually investigate his flagged orders, there is no reasonable basis to conclude that the results produced by Method A—which are contrary to common sense and record evidence—are reliable or helpful to the finder of fact.

For many of the same reasons, Method B is likewise unreliable and unhelpful. Other than the flawed due diligence assumption, Methods A and B share ***all*** of the flaws discussed above, and so Defendants' critiques apply equally to both. *See supra* p.7. Moreover, the ***400% error rate*** between Method A and Method B calls into question the reliability of both methodologies. *See infra* p.28. Accordingly, Method B should likewise be excluded.

B. Mr. Rafalski's Flagging Methodologies Fail All Four *Daubert* Factors.

In assessing the reliability and admissibility of putative expert testimony, courts look to four factors first identified by the Supreme Court in *Daubert*: "(1) whether [the] theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether [the] technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Cooper*, 259 F.3d at 199 (citing *Daubert*, 509 U.S. at 592–94). By Mr. Rafalski's own admission, his flagging methodologies fail all four factors.

Accordingly, those methodologies should be excluded under Rule 702. *See, e.g.*, *Black v. Rhone-Poulenc, Inc.*, 819 F. Supp. 2d 592, 606 (S.D.W. Va. 1998) (excluding testimony of expert who failed every *Daubert* reliability factor); *see also Small v. WellDyne, Inc.*, 927 F.3d 169, 177 (4th Cir. 2019) ("Without testing, supporting literature in the pertinent field, peer reviewed publications or some basis to assess the level of reliability, expert opinion testimony can easily, but improperly, devolve into nothing more than proclaiming an opinion is true 'because I say so.'").

Testing. The first *Daubert* factor asks whether the methodology "can be or has been tested." *Id.* On cross-examination, Mr. Rafalski conceded that his proposed methodologies have never been tested, admitting that neither DEA nor anyone else in the real world has ever used them, that he has never even recommended that anyone do so, and that he cannot substantiate his methods by tying his flagged orders to actual harm. *See supra* p.5–6. In fact, the exact opposite is true—Mr. Rafalski admitted that he created the proposed methodologies for purposes of litigation and that he has never used them for any purposes other than as a paid expert witness. *Id.*[20]

Peer Review. The second *Daubert* factor asks whether the methodology "has been subjected to peer review and publication." *Cooper*, 259 F.3d at 199. Mr. Rafalski conceded that he has never attempted to have any of his proposed methodologies published or peer reviewed.

[20] *See, e.g.*, *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("One very significant fact to be considered is whether the experts … have developed their opinions expressly for purposes of testifying.… [I]n determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office."); *Mike's Train House, Inc. v. Lionel, L.L.C.*, 472 F.3d 398, 408 (6th Cir. 2006) ("We have been suspicious of methodologies created for the purpose of litigation.… That this methodology was created for the purposes of litigation further supports our conclusion that [the putative expert's] testimony was not reliable under *Daubert*."); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 670 (S.D.W. Va. 2014) (noting that whether methodology was created for purposes of litigation "does have a role in applying *Daubert*," and concluding that courts should "consider the independence of an expert's testimony as evidence that his research comports with the dictates of good science").

5/26 Tr. at 223:12–17 ("Q. [H]ave you taken these stylized illustrations that were created for litigation and tried to publish them so they could be peer-reviewed and available for criticism and use if they were actually valuable? A. I have not done that, Your Honor."). Nor is there any evidence that his methodologies were based on peer-reviewed methodologies developed by others.

Error Rate. The third *Daubert* factor asks whether the methodology "has a high known or potential rate of error." *Cooper*, 259 F.3d at 199. It is self-evident that Mr. Rafalski's six methodologies produce wildly different numbers of flagged orders. *See* 5/26 Tr. at 96:13–101:21 (reciting Dr. McCann's analysis of how many orders are flagged by each methodology). Indeed, even as between the two methodologies Mr. Rafalski did not affirmatively disavow on cross-examination—Methods A and B—Mr. Rafalski conceded that there is an "over 400 percent" error rate, which results in a "big difference" in flagged orders. 5/26 Tr. at 219:10–22.

General Acceptance. The fourth *Daubert* factor asks whether the methodology "enjoys general acceptance within a relevant scientific community." *Cooper*, 259 F.3d at 199. Mr. Rafalski admitted that neither Method A nor Method B is generally accepted in the field of controlled substance diversion monitoring or control. *See* 5/26 Tr. at 236:12–15 ("Q. There's no general acceptance you can point me to for Method A with its due diligence assumption, whether it's by distributors, regulators or academics, correct? A. That is a correct statement, Your Honor), 242:1–5 ("Q. And you can't point me to any generally accepted methodology for identify and reporting suspicious orders that ignores entirely what the medical community is doing in terms of increased legitimate prescriptions, true? A. That's a correct statement."). The lack of general acceptance for Mr. Rafalski's litigation-created methodologies is unsurprising, given that none of them has ever been used in the real world to identify suspicious orders. *See supra* p.5–6, 27.

* * *

In sum, Mr. Rafalski's flagging methodologies—which produce self-evidently implausible and unreliable results—fail all four *Daubert* factors for assessing the reliability of expert opinions. Given Mr. Rafalski's failure to explain the basis of his methodologies or provide any factual support for their results, his flagging opinions should be excluded under Rule 702.

C. Plaintiffs' Attempt To Rewrite Mr. Rafalski's Testimony Does Not Save It From Exclusion.

After the Court expressed "shock" at Mr. Rafalski's testimony that Defendants should have blocked more than 90% of the orders they received from pharmacies in Cabell/Huntington, Plaintiffs' counsel attempted to rescue Mr. Rafalski's testimony by re-characterizing it. Even if counsel's representations were consistent with Mr. Rafalski's own sworn testimony (they are not), they could not save Mr. Rafalski's opinions from exclusion.

Plaintiffs' counsel first told the Court that that Mr. Rafalski "was not suggesting that all of those pills are suspicious." 5/27 Tr. at 60:14–16. That is half true. On the one hand, Mr. Rafalski repeatedly suggested that his flagged orders were "suspicious." *See, e.g.*, 5/26 Tr. at 84:14–19 ("Q. What's the purpose of flagging certain orders? A. We're trying to identify an order, Your Honor, that has a suspicion of diversion, that is outside of what's normal and what's usual."). On the other hand, Mr. Rafalski promptly abandoned this claim upon first challenge, admitting that his flagging methodologies ***do not identify orders that meet the regulatory definition of "suspicious orders"***:

> Q…. Do you know how many of these tens of millions of [flagged] orders should have been reported to the DEA as suspicious?
>
> A. No, I do not.

5/26 Tr. at 229:24–230:2. But that admission does not help Plaintiffs; it is fatal.

According to Plaintiffs, Defendants had a duty to block orders that were suspicious *as that term is used in the governing regulations*. Mr. Rafalski's express disavowal of the proposition

that his flagged orders meet the regulatory definition of "suspicious orders" renders his opinions utterly irrelevant to the case. Neither Mr. Rafalski nor Plaintiffs have identified any basis for concluding that orders which do not meet the regulatory definition of suspicious—but that are deemed "suspicious" in some colloquial sense by Mr. Rafalski—may not be shipped. Nor could they.

Plaintiffs' counsel also stated that Mr. Rafalski was "not suggesting [that flagged] pills should be blocked." 5/27 Tr. at 60:14–16. That is contrary to Mr. Rafalski's testimony. *See, e.g.*, 5/26 Tr. at 79:10–13, 97:7–18, 97:19–24 (testifying that flagged orders should be blocked). And, in any event, that characterization does nothing to save Mr. Rafalski's testimony. If in fact Mr. Rafalski's flagged orders do not purport to represent orders that Defendants should have blocked, then *by definition* Mr. Rafalski's opinions cannot show that Defendants did anything wrong in shipping those orders. Accordingly, to the extent that Plaintiffs do not now offer Mr. Rafalski's flagging methodologies as evidence of orders that Defendants should not have shipped, the Court should exclude Mr. Rafalski's testimony as irrelevant and unhelpful to the trier of fact.

CONCLUSION

For the foregoing reasons, the Court should exclude Mr. Rafalski's unreliable opinions pursuant to Rule 702.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 31st day of May, 2021, the foregoing "MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' RENEWED *DAUBERT* MOTION TO EXCLUDE THE OPINIONS OF JAMES E. RAFALSKI" was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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